Dennis J. Reich, TX Bar No. 16739600
Debra Brewer Hayes, TX Bar No. 05656790
Susan L. Fuller, TX Bar No. 24032212
4265 San Felipe Blvd, Suite 1000
Houston, Texas 77027
Telephone: (713) 622-7271
Facsimile: (713) 623-8724

Attorneys for Plaintiffs

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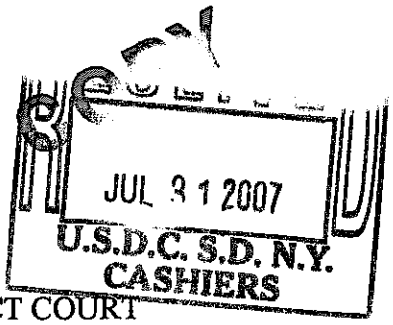

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	MDL No. 1:06-md-1789- JFK
ANNIE DANIELS, Plaintiff, v. MERCK & CO., INC. (hereinafter "Merck"), a New Jersey Corporation Defendant.	Case No. _____ **CIVIL COMPLAINT** **JURY TRIAL DEMANDED**

ANNIE DANIELS, Plaintiff, by and through her undersigned counsel, sue Defendant Merck & Co., Inc. and allege as follows:

I. PARTIES

1. Plaintiff is a resident of the State of Texas, and Defendant, Merck, is incorporated and has its primary place of business in the State of New Jersey.

2. Plaintiff, ANNIE DANIELS, was born May 31, 1936, and is a resident of Dallas, Dallas County, Texas. (Unless otherwise specified herein, the term "Plaintiff" as used in the

singular refers to Plaintiff, ANNIE DANIELS.) After taking FOSAMAX for an extended period of time, Plaintiff was diagnosed with serious and permanent injuries.

3. Defendant, Merck, is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's principal office is located at One Merck Drive, Whitehouse Station, New Jersey.

4. Defendant, Merck, was at all relevant times authorized to conduct business in the State of Texas.

5. Defendant has regularly transacted business in the State of Texas and continues to do so.

6. At all relevant times, Defendant, Merck, through its agents, servants, employees, and apparent agents, was the designer, manufacturer, marketer, distributor, and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Paget's Disease.

7. Defendant, Merck, either directly or through its agents, apparent agents, servants, or employees, at all relevant times, sold and distributed FOSAMAX in the State of Texas.

8. Defendant encouraged the use of this drug in improper customers, misrepresented the safety and effectiveness of this drug, and concealed or understated its dangerous side effects in Texas. The Defendant aggressively marketed this drug directly to the consuming public through the use of various marketing mediums including, but not limited to, print and television advertisements in Texas.

9. Based on information and belief, Sales Representatives called physicians on numerous occasions at which times they presented fraudulent information regarding the safety and efficacy of FOSAMAX and its harmful side effects, and/or fraudulently suppressed material information regarding the safety and efficacy of FOSAMAX and its harmful side effects, and/or

placed FOSAMAX in the stream of commerce by providing Plaintiff's physician(s) samples of the drug FOSAMAX.

10. At all times material hereto, Merck advertised, marketed, and/or produced FOSAMAX to Plaintiff utilizing information known to fraudulently represent the safety and efficacy of FOSAMAX, and said Defendant failed to warn of the known dangers and adverse events associated with the use of the drug FOSAMAX.

11. At all times relevant hereto, the Defendant actually knew of the defective nature of its product as herein set forth yet continued to design, manufacture, market, distribute, and sell the product in Dallas County, Texas.

12. Defendant derives substantial revenue from pharmaceutical products used or consumed in the State of Texas.

13. Defendant expected, or should have expected, that its business activities could or would have consequences within the State of Texas.

14. Defendant placed FOSAMAX into the stream of worldwide commerce and interstate commerce in the United States. They did so without adequate testing and with no warning that the drug carried with it a risk of causing osteonecrosis or osteomyelitis of the jaw.

15. Plaintiff needs continued medical monitoring to treat serious and permanent injuries which have already manifested.

II. JURISDICTION AND VENUE

16. This court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity exists between Plaintiff and Defendant.

17. Plaintiff is a resident of the state of Texas.

18. Defendant, Merck & Co., Inc., is incorporated and has its primary place of

business in the State of New Jersey. The amount in controversy, exclusive of interests and costs, exceeds $75,000.00.

19. Venue is proper within this district and division pursuant to agreement of the parties.

III. FACTUAL BACKGROUND

20. Merck, either directly or through its agents, apparent agents, servants, or employees, designed, manufactured, marketed, advertised, distributed, and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other uses.

21. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff, ANNIE DANIELS, have suffered and may continue to suffer severe and permanent personal injuries, including osteonecrosis and osteomyelitis.

22. Merck concealed and continues to conceal its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff, ANNIE DANIELS, other consumers, and the medical community.

23. Merck failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.

24. As a result of Defendant's actions and inaction, Plaintiff, ANNIE DANIELS, was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks compensatory damages, as well as other damages.

25. At all relevant times, Merck was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

26. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate for various uses including the treatment of osteoporosis and Paget's disease. Defendant, Merck, markets alendronate under the name FOSAMAX.

27. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

28. There are two classes of bisphosphonates: the N-containing (nitrogenous) and nonN-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia), ibandronate (Bondronat), and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel), clodronate (Bonefos and Loron), and tiludronate (Skelid). Alendronate contains a nitrogen atom. The Physicians Desk Reference ("PDR") for FOSAMAX confirms that the molecule contains a nitrogen atom.

29. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse event profile to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

30. Merck knew, and or should have known, that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew, or should have known,

that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

31. Merck also knew, or should have known, that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That, in turn, can progress to widespread necrosis (bone death) and osteomyelitis (infection of the bone).

32. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.

33. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and typically is not reversible.

34. Shortly after Merck began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Merck failed to implement further study regarding the risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

35. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

36. Since FOSAMAX was released, the FDA has received a significant number of reports of osteonecrosis of the jaw among users of FOSAMAX.

37. On August 25, 2004, the United States Food & Drug Administration ("FDA") posted its ODS Postmarketing Safety Review on bisphosphonates - - specifically, pamidronate

(Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX).

38. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, FOSAMAX.

39. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Defendant, Merck, to specifically warn about the risk of osteonecrosis of the jaw. Defendant, Merck, has refused to accede to the FDA's request and to this day still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.

40. Rather than warn patients, and despite knowledge known by Defendant about increased risk of osteonecrosis of the jaw in patients using FOSAMAX, Defendant continues to defend FOSAMAX, mislead physicians and the public, and minimize unfavorable findings.

41. FOSAMAX is one of Merck's top selling drugs, averaging more than $3 billion a year in sales.

42. Consumers, including Plaintiff, ANNIE DANIELS, who has used FOSAMAX for the treatment of osteoporosis, have several alternative, safer products available to treat the conditions.

43. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff, ANNIE DANIELS, or the medical community of such risks.

44. In an elaborate and sophisticated manner, Defendant aggressively marketed FOSAMAX directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payers, medical care organizations, and large institutional buyers (e.g., hospitals) to include FOSAMAX on their formularies. Faced

with the increased demand for the drug by consumers and health care professionals that resulted from Defendant's successful advertising and marketing blitz, third party payers were compelled to add FOSAMAX to their formularies. Defendant's marketing campaign specifically targeted third party payers, physicians, and consumers and was designed to convince them of both the therapeutic and economic value of FOSAMAX.

45. As a direct result, Plaintiff, ANNIE DANIELS, was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff, ANNIE DANIELS, requires and will in the future require ongoing medical care and treatment.

46. Plaintiff, ANNIE DANIELS, has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the Plaintiff's use of FOSAMAX.

47. Plaintiff, ANNIE DANIELS, was prescribed and began taking FOSAMAX in June 2004.

48. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.

49. As a direct and proximate result of using FOSAMAX, Plaintiff suffered development of serious and permanent injuries.

50. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

51. Plaintiff used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

52. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug.

53. Merck, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Merck's fraudulent concealment.

54. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware and could not have reasonably known or have learned through reasonable diligence that Plaintiff had been exposed to the risks identified in this complaint and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

IV. EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

55. The running of any statute of limitations has been tolled by reason of Defendant's fraudulent concealment. Defendant, through its affirmative misrepresentation and omissions, actively concealed from Plaintiff and her prescribing physician the true risks associated with taking FOSAMAX.

56. As a result of Defendant's actions, Plaintiff and, upon information and belief, her prescribing physician were unaware, and could not reasonably know or have learned through reasonable diligence, that she had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendant's acts and omissions.

57. Furthermore, Defendant is estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality, and nature of FOSAMAX. Defendant was under a duty to disclose the true character, quality, and nature of FOSAMAX because this was non-public information over which the Defendant had and continues to have exclusive control and because the Defendant knew that this information was not available to the plaintiffs, medical providers, and/or to their facilities. In addition, the Defendant is estopped from relying on any statute of limitations because of their international concealment of these

facts.

58. The Plaintiff had no knowledge that the Defendant was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendant, the Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. The Defendant had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent, and identity of related health risks and were forced to rely on only the Defendant's representations.

COUNTS

COUNT I: NEGLIGENCE

59 Plaintiff restates the allegations set forth above as if fully rewritten herein.

60. The Defendant owed Plaintiff, ANNIE DANIELS, and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

61. The Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test FOSAMAX before releasing the drug to market;

b. Failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX.

c. Failing to conduct sufficient post-market testing and surveillance of FOSAMAX;

d. Designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. Failing to exercise due care when advertising and promoting FOSAMAX; and

f. Negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

g. Defendant know, or should have known, that consumers, including Plaintiff, would suffer injuries as a result of Defendant's failure to exercise ordinary care.

62. As a direct and proximate consequence of Defendant's actions, negligence, omissions, and misrepresentations, Plaintiff, ANNIE DANIELS, has sustained serious and permanent injuries and will continue to suffer injury, harm, and economic loss.

63 Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter Defendant from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II: STRICT LIABILITY

64. Plaintiff restates the allegations set forth above as if fully rewritten herein.

65. Merck manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a

defective and unreasonably dangerous condition to consumers, including Plaintiff, ANNIE DANIELS. As such, Defendant had a duty to warn the using public, including Plaintiff, of the health risks associated with using the product.

66. Merck designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by the Defendant.

67. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

68. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

69. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

70. FOSAMAX was defective in design or formation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

71. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warning adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

72. Although Defendant knew, or should have known, of the defective nature of FOSAMAX, Merck continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Merck acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

73. Plaintiff could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug. Plaintiff would not have used FOSAMAX had the Defendant properly disclosed the risk associated with the drug.

74. As a direct and proximate consequence of Defendant's actions, negligence, omissions, and misrepresentations, Plaintiff, ANNIE DANIELS, has sustained serious and permanent injuries and will continue to suffer injury, harm, and economic loss.

75. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter Defendant from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III: BREACH OF EXPRESS WARRANTY

76. Plaintiff restates the allegations set forth above as if fully rewritten herein.

77. Defendant expressly represented to Plaintiff, ANNIE DANIELS, and other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes- that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

78. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous side effects, and causes severe and permanent injuries.

79. At all relevant times, FOSAMAX did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

80. Plaintiff, ANNIE DANIELS, other consumers, and the medical community relied

upon Defendant's express warranties.

81. As a direct and proximate consequence of Defendant's actions, negligence, omissions, and misrepresentations, Plaintiff, ANNIE DANIELS, has sustained serious and permanent injuries and will continue to suffer injury, harm, and economic loss.

82. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter Defendant from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IV: BREACH OF IMPLIED WARRANTY

83. Plaintiff restates the allegations set forth above as if fully rewritten herein.

84. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.

85. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

86. Merck was aware that consumers, including Plaintiff, ANNIE DANIELS, would use FOSAMAX for treatment of osteoporosis and for other purposes.

87. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

88. Defendant breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.

89. Consumers, including Plaintiff, and the medical community reasonably relied upon Defendant's implied warranty of FOSAMAX.

90. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

91. As a direct and proximate consequence of Defendant's actions, negligence, omissions, and misrepresentations, Plaintiff, ANNIE DANIELS, has sustained serious and permanent injuries and will continue to suffer injury, harm, and economic loss.

92. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V: FRAUDULENT MISREPRESENTATIONS

93. Plaintiff restates the allegations set forth above as if fully rewritten herein.

94. Merck made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing, materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the prevention and treatment of osteoporosis; and

b. Defendant represented that FOSAMAX was safer than other alternative medications.

95. Defendant knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.

96. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

97. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

98. Plaintiff's doctors and others relied upon the representations.

99. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

100. As a direct and proximate consequence of Defendant's actions, negligence, omissions, and misrepresentations, Plaintiff, ANNIE DANIELS, has sustained serious and permanent injuries and will continue to suffer injury, harm, and economic loss.

101. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI: FRAUDULENT CONCEALMENT

102. Plaintiff restates the allegations set forth above as if fully rewritten herein.

103. Merck's fraudulently concealed information with respect to FOSAMAX in the

following particulars:

a. Merck represented through its labeling, advertising, marketing, materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

b. Merck represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.

104. Merck had sole access to material facts concerning the dangers and unreasonable risks of FOSAMAX.

105. The concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.

106. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

107. Plaintiff's doctors and others relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's doctors and Plaintiff.

108. As a direct and proximate consequence of Defendant's actions, negligence, omissions, and misrepresentations, Plaintiff, ANNIE DANIELS, has sustained serious and permanent injuries and will continue to suffer injury, harm, and economic loss.

109. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish

Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII: PUNITIVE DAMAGES

110. Plaintiff restates the allegations set forth above as if fully rewritten herein.

111. Merck has repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations relating to public hazards about which the public should be warned.

112. For instance, in March 2000, Merck completed a study called VIGOR (VIOXX Gastrointestinal Outcomes Research) relating to its prescription cox-2 inhibitor, VIOXX. The VIGOR study showed that VIOXX patients had more than double the rate of serious cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory drug. The study was published in the *New England Journal of Medicine.*

113. In September 2001, the FDA warned Merck to stop misleading doctors about VIOXX's effect on the cardiovascular system. Defendant, Merck, was admonished to stop minimizing the risks of the drug in its marketing. Despite that, Defendant, Merck, refused to adequately warn physicians and patients about the risk of heart attacks while taking VIOXX.

114. On August 25, 2004, a representative from the FDA presented results of a database analysis of 1.4 million patients. The analysis demonstrated that VIOXX users were more likely to suffer a heart attack or sudden cardiac death than those taking older non-steroidal drugs. The FDA representatives concluded that VIOXX was linked to more than 27,000 heart attacks or sudden cardiac deaths nationwide from the time it came on the market in 1999 through 2003.

115. On August 26, 2004, Merck released a press statement which refuted the FDA analysis and restated Merck's support for the cardiovascular safety of VIOXX.

116. On September 30, 2004, Merck recalled VIOXX from the market after having to halt the APPROVe study (Adenomatous Polyp Prevention on Vioxx). The study was underway to evaluate the use of VIOXX for recurrent colon polyps. The researchers found an alarming number of cardiovascular events among the drug users in the APPROVe study.

117. At the same time, Merck was aware that the FDA, as of August 24, 2004, was advising Merck to warn about the risk of osteonecrosis of the jaw for its FOSAMAX patients. Because Merck knew that its blockbuster drug VIOXX was about to be pulled from the market, placing more importance on the $3 billion annual sales of FOSAMAX, Merck deliberately chose to not amend its packaging of FOSAMAX to include the risk of osteonecrosis of the jaw, fearing that such a warning would result in reduced revenues for its second largest income producer, FOSAMAX.

118. Merck's acts were willful and malicious in that Merck's conduct was carried on with a conscious disregard for the safety and rights of Plaintiffs. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Merck in an amount appropriate to punish Merck and deter similar conduct in the future.

119. Although Defendant knew or recklessly disregarded the fact that the subject product causes debilitating and potentially lethal side effects, Defendant continued to market the subject product to consumers, including Plaintiff, without disclosing these side effects.

120. Defendant knew of the subject product's defective nature, as set forth herein, but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the subject product.

121. Defendant intentionally concealed or recklessly failed to disclose to the public, including Plaintiff, the potentially life-threatening side effects of the subject product to ensure

their continued and increased sales. This intentional and/or reckless failure to disclose information deprived Plaintiff of the information necessary for her to weigh the true risks of using the subject product against the benefits.

122. Defendant's aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX
Products Liability - Failure to Warn

123. The foregoing paragraphs of this Complaint are realleged and incorporated by reference.

124. Defendant designed, tested, manufactured, marketed, sold and/or distributed FOSAMAX. As such, it had a duty to warn the using public, including Plaintiff, of the health risks associated with using the subject product.

125. The subject product was under the exclusive control of Defendant and was unaccompanied by appropriate warnings regarding the health risks associated with its use, including osteonecrosis of the jaw. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injury to the consumer. The promotional activities of Defendant further diluted or minimized the warnings given with the product.

126. The subject product was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings insufficient to alert Plaintiff to the

dangerous risks and reactions associated with it, including, but not limited to osteonecrosis of the jaw. Even though Defendant knew or should have known of the risks and reactions associated with the subject product, it still failed to provide warnings that accurately reflected the signs, symptoms, incidence, scope, or severity of these risks.

127. Plaintiff used the subject product for its intended purpose, i.e. for the prevention or treatment of osteoporosis.

128. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

129. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant had knowledge of the dangerous risks and side effects of the subject product.

130. Plaintiff did not have the same knowledge as Defendant and no adequate warning was communicated to her.

131. Defendant had a continuing duty to warn consumers, including Plaintiff, of the dangers associated with the subject product. By negligently and/or wantonly failing to adequately warn of the dangers of use of the subject product, Defendant breached its duty.

132. Although Defendant knew of the defective nature of the subject product, they continued to design, manufacture, market, and sell it without providing accurate, adequate, and complete warnings concerning its use so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by the subject product.

133. As a direct and proximate result of the Defendant's failure to adequately warn or other wrongdoing and actions of Defendant described herein, Plaintiff has sustained serious and permanent injuries, and will continue to suffer injury, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendant as follows:

1. General damages in an amount to be proven at the time of trial;
2. Special damages in an amount to be proven at the time of trial;
3. Exemplary and punitive damages in an amount to be proven at the time of trial and sufficient to punish Defendant or to deter Defendant and others from repeating the injurious conduct alleged herein;
4. Pre-judgment and post-judgment interest on the above general and special damages;
5. For costs of this suit and attorney's fees;
6. All other relief to which Plaintiff may be entitled;
7. That the costs of this action be taxed to Defendant;
8. That Plaintiff be granted reasonable attorneys' fees and costs as provided by law; and
9. For such other and further relief as the Court may deem just and proper.

Dated: 7/30/07

REICH & BINSTOCK, LLP

By: Dennis C. Reich

Dennis C. Reich, TX Bar No. 16739600
Debra Brewer Hayes, TX Bar No. 05656790
Susan L. Fuller, TX Bar No. 24032212
4265 San Felipe Blvd, Suite 1000
Houston, Texas 77027
Telephone: (713) 622-7271
Facsimile: (713) 623-8724

Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all claims so triable in this action.

Dated: 7/30/07

REICH & BINSTOCK, LLP

By: Dennis C. Reich

Dennis C. Reich, TX Bar No. 16739600
Robert J. Binstock, TX Bar No. 02328350
Deborah L. Ziegler, TX Bar No. 12219200
4265 San Felipe Blvd, Suite 1000
Houston, Texas 77027
Telephone: (713) 622-7271
Facsimile: (713) 623-8724

Attorneys for Plaintiffs